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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/457,771	12/09/1999	R. MARTIN EMANUELE	19720-0624	8054

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EXAMINER	
SCHNIZER, RICHARD A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/457,771	EMANUELE ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,7,9-12,14,15,18,19,21-25 and 27-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *37* is/are allowed.

6)☒ Claim(s) *1-4,6,7,9-12,14,15,18,19,21-25,27-36 and 3842* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

An amendment was received on 1/13/05.

Claims 17, 20, and 26 were cancelled and claims 34-42 were added as requested.

Claims 1-4, 6, 7, 9-12, 14, 15, 18, 19, 21-25, and 27-42 are pending and under consideration in this Office Action.

Drawings

The drawings filed 1/3/05 are accepted by the Examiner.

Rejections Withdrawn

The rejections of claims 1-4, 6-12, 14-31, and 34 under 35 USC 112, second paragraph are withdrawn in view of Applicant's amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 is indefinite because it is unclear what are the metes and bounds of "approximately less than".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claims 1, 6, 7, 9, 14, 15, 18, 19, 21-25, 27-36, and 38-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 6, 7, 9, 14, 15, 18, 19, 21-25 and 27-31 recite the limitation "the polyoxyethylene portion of the block copolymer is approximately 1% to approximately 45% of the total weight of the block copolymer". The specification provides no written support for this particular range, so it represents new matter. The specification provides written support for 1% to 50%, and for 5% to 20%, but does not provide support for the range of 1-45%, and there is no evidence that Applicant contemplated this specific range at the time the invention was filed.

Claims 32 and 33 recite the limitation "the polyoxyethylene portion of the block copolymer is approximately 1% to approximately less than 45% of the total weight of the

block copolymer". The specification provides no written support for this particular range, so it represents new matter. These claims also require that the hydrophobe portion must be between approximately 750 and 1000 Da. The specification provides no written support for this range. As such, there is no evidence that Applicant contemplated this specific range at the time the invention was filed, and it represents new matter.

Claim 33 requires that the polyoxyethylene portion of a block copolymer must be "approximately 10% -30% of the total weight of the block copolymer. The specification provides no written support for this range, and there is no evidence that Applicant contemplated this specific range at the time the invention was filed, so it represents new matter.

Claims 34-36 require that the polyoxypropylene portion of a copolymer must be "between approximately 4400 and 15000 Daltons". The specification provides no written support for this range, and there is no evidence that Applicant contemplated this specific range at the time the invention was filed, so it represents new matter.

Claims 41 and 42 recite the range "between approximately 4740 and 15,000 Daltons." The specification provides no written support for this range, and there is no evidence that Applicant contemplated this specific range at the time the invention was filed, so it represents new matter.

Response to Arguments

Applicant's arguments filed 1/13/05 have been fully considered but they are not persuasive.

Applicant addresses the new matter rejections at pages 12 and 13 of the response. Applicant provides evidence that polymers are disclosed in the specification that are at or near the molecular weights recited in the claims. However, this does not amount to a disclosure of a preferred range of molecular weights, such as is claimed. In the absence of such support, the claimed ranges constitute new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 9-12, 19 stand rejected under 35 U.S.C. 102(e) as being anticipated by Allison et al (US Patent 5,376,369, issued 12/27/94) as evidenced by .

Allison taught that Pluronics L101, L121, and L122, could be used as an adjuvant in the delivery of whole viruses in vivo as vaccines (see abstract, and column 23, lines 24-55, especially, lines 30, 31, 34, 36, 38, 46, and 55). Note that L101 and L122 are the trade names for CRL 8131 and CRL 8142, respectively (recited in claims 4 and 12 see also e.g. Table II at page 17 of instant specification). Whole viruses comprise nucleic acids encoding genes, and can be considered expression vectors. The limitation requiring an expression vector capable of expressing the genes is anticipated by the viruses themselves, which are clearly capable of expressing their own genes.

Because the viruses comprise genes required for viral transcription, they comprise genes that are used for altering gene activity, particularly during the process of viral amplification

Thus Allison anticipates the claims.

Claims 1-3, 9-11, 19, and 21 stand rejected under 35 U.S.C. 102(e) as being anticipated by Wasmoen et al (US Patent 5,656,275, issued 8/12/97), as evidenced by Osorio et al (WO 99/39733, issued 8/12/99).

Wasmoen taught that Pluronic L121 could be used as an adjuvant in the delivery of whole viruses in vivo (see column 3 line 66 to column 4, line 28). Whole viruses comprise nucleic acids encoding genes, and can be considered expression vectors. To the extent that the viruses must be propagated in order to make the disclosed vaccines, the nucleic acids are amplified. The limitation requiring an expression vector capable of expressing the genes is anticipated by the viruses themselves, which are clearly capable of expressing their own genes. The compositions can be considered to comprise an antimicrobial drug (claim 18) in the form of viral antigens. Because the viruses comprise genes required for viral transcription, they comprise genes that are used for altering gene activity, particularly during the process of viral amplification. The viruses are modified to express foreign antigens for the purpose of providing an immune response against the antigens. It is noted that Wasmoen exemplifies a virus in which the antigen is expressed and incorporated into the viral particle, prior to administration of the virus to a recipient animal. However, a review of the art indicates that the virus of Wasmoen should be capable of infecting cells in vivo and subsequently producing a foreign antigen in infected cells in vivo, thereby meeting the limitations of claims 21 and 29. See Osorio et al who teach recombinant raccoon poxviruses similar to those of

Wasmoen, containing foreign genes encoding antigens and immunomodulatory factors for expression in the recipient (page 6, line 22 to page 7, line 10, page 7, line 21 to page 8, line 7, page 10, lines 4-22.

Thus Wasmoen anticipates the claims.

Response to Arguments

Applicant's arguments filed 1/13/05 have been fully considered but they are not persuasive.

Applicant addresses the rejections at pages 13 and 14 of the response. Applicant argues that deletion of "expression vector" from the claims overcomes the rejections. This is unpersuasive because the claims still recite "genes", and the viruses of Allison and Wasmoen both encode genes. The rejections are maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6, 7, 9, 14, 15, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wasmoen et al (US Patent 5,656,275, issued 8/12/97) in view of Miyamura et al (US Patent 5,372,928, issued 12/13/94).

Wasmoen taught that Pluronic L121 could be used as an adjuvant in the delivery of whole virus vaccines in vivo (see column 3 line 66 to column 4, line 28). Whole

viruses comprise nucleic acids encoding genes, and can be considered expression vectors. To the extent that the viruses must be propagated in order to make the disclosed vaccines, the nucleic acids are amplified. Note that L121 has a hydrophobe molecular weight of about 4400, which is within 10% of the recited "approximately 4400", and so is considered to be within the claimed range. The hydrophile percentage of L121 is about 10%.

Wasmoen did not teach the addition a surfactant and an alcohol to the vaccine.

Miyamura teaches that vaccine compositions are often modified by the addition of ethanol and Tween 80. See e.g. column 19, lines 5-22. Arriving at the appropriate concentrations of these additives is considered to be routine optimization.

Thus the invention as a whole was prima facie obvious.

Response to Arguments

Applicant's arguments filed 1/13/05 have been fully considered but they are not persuasive.

Applicant addresses the rejections at pages 13 and 14 of the response. Applicant argues that deletion of "expression vector" from the claims overcomes the rejections. This is unpersuasive because the claims still recite "genes", and the viruses of Allison and Wasmoen both encode genes. The rejections are maintained.

Conclusion

Claims 37 is allowable. Claims 18, 22-25, 27-33, and 35-42 are free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Richard Schnizer, Ph.D.

DAVE T. NGUYEN
PRIMARY EXAMINER